K053438

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 18 2006

Submitter

Company:	3M ESPE AG
Street:	ESPE Platz
ZIP-Code, City:	D-82229 Seefeld
Federal State:	Bavaria
Country:	Germany
Establishment Registration Number:	9611385
Official Correspondent:	Dr. Andreas Petermann, Manager Regulatory Affairs
Phone:	011-49-8152-700 1395
Fax:	011-49-8152-700 1869
E-mail:	andreas.petermann@mmm.com
Date:	December 7, 2005

Name of Device

Proprietary Name:	GLASS CERAMICS
Classification Name	Porcelain powder for clinical use
Common Name:	Glass ceramic blocks

Predicate Devices:

Lava Ceram™ / Lava Frame™ by 3M ESPE (K0113949)

Paradigm™ MZ 100 block by 3M ESPE (K9204259)

ProCAD® by Ivoclar Vivadent Inc. (presumably K980986)

VITABLOCS® Mark II by VITA Zahnfabrik H. Rauter GmbH & Co. KG (presumably K022408)

Description for the Premarket Notification

GLASS CERAMICS are classified as Porcelain powder for clinical use (21 C.F.R. §872.6660). They are glass ceramic blocks intended to manufacture all-ceramic inlays, onlays, crowns, and veneers. GLASS CERAMICS blocks are available in six colors (A1; A2; A3; A3.5; B3; Enamel) and five sizes (I8, I10, I12, I14, V5-12).

Like the predicate devices, the glass ceramic blocks "ProCAD® blocks" and "VITABLOCS® Mark II" and the composite block "Paradigm™ MZ 100" blocks, GLASS CERAMICS blocks are grindable blocks for CAD/CAM systems. The all-ceramic restoration is produced in the dentist's office using the CEREC® system or in a dental laboratory using CEREC® Inlab; both systems are manufactured by the company Sirona, Bensheim, Germany (K012517). The clinical situation is optically scanned and then processed by the CEREC® 3D software. The restoration is fabricated in the CEREC® grinding unit.

Comparison to the predicate devices for composition, performance data and indications for use shows that GLASS CERAMICS are substantially equivalent to the predicate devices. In summary it can be concluded that safety and effectiveness requirements for GLASS CERAMICS are fully met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2006

Dr. Sabine Krischer
Regulatory Affairs Specialist
3M ESPE AG
ESPE Platz
Seefeld, D-82229
GERMANY

Re: K053438
Trade/Device Name: Glass Ceramics
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: December 07, 2005
Received: December 09, 2005

Dear Dr. Krischer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053438

Device Name: Glass Ceramics
Indications for Use:

Manufacture of all-ceramic inlays, onlays, crowns, and veneers.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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